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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,755	03/26/2004	Michael J. Renzi	PRD2052USNP	9072

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EXAMINER	
DEBERRY, REGINA M	
ART UNIT	**PAPER NUMBER**
1647	

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05/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,755	RENZI ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *25-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

Applicant's election without traverse of Group I (claims 1-24) in the reply filed on 16 February 2007 is acknowledged. Claims 25-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 16 February 2007. Claims 1-24 are under examination.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed 28 November 2005 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because of the recitation, " a dosing regimen of erythropoietin for promoting recovery after an ischemic event comprising, administering

to a subject..." It is not clear if the instant claims are drawn to a method, a composition or information/instructions. If the instant claims are drawn to a method of treating, then claims 1-13 read on the same scope and thus are duplicates of claims 14-23. If claims 1-13 are information or instructions, Applicants are reminded that information and instructions are non-statutory since written material is a form of intellectual property protectable by copyright, not patents. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6, 10, 13-19, 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Ehrenreich et al. (reference submitted by Applicant, Molecular Medicine 8(8):495-505, 2002).

Ehrenreich et al. teach the intravenous infusion of recombinant human erythropoietin (rhEPO) (3.3×10^4 IU/50ml/30min, for a total dose of 100,000 IU), starting within 8 hr of initial stroke symptoms, continuing on 3 consecutive days (24 and 48 hours later) after stroke. Cerebrospinal fluid (CSF) sampling was performed on day 2 after the second infusion (page 497, 2nd paragraph, 498, 1st paragraph and page 499, 2nd paragraph). Ehrenreich et al. teach that rhEPO treated patients improved earlier

(page 500) and had reduced brain infarction (page 501 and Figure 4) compared to placebo treated patients.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 13-21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ehrenreich, (reference submitted by Applicant, CA 2 353 553 A1). Ehrenreich teaches a method for treating cerebral ischaemia comprising intravenously administering rhEPO (abstract and pages 1 and 3 and claims). Ehrenreich teach dosage amounts from 5,000 to 100,000 units within 8 hours after the stroke (page 4, 4th paragraph and claims). Ehrenreich teaches the administration of 35,000 units of EPO 8 hours, 24 hours and 48 hours after the stroke (bottom of page 5-top of page 6; page 7 and claims). Ehrenreich teaches a reduction in ischaemic infarction in EPO treated patients (page 7, last paragraph and Figure 2C).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 11, 12, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrenreich, (CA 2 353 553 A1) as applied to claims 1 and 14 above, and further in view of Alafaci et al. (reference submitted by Applicant, European Journal of Pharmacology, 406:219-225, 2000) and Brines et al. (reference submitted by Applicant, PNAS, Vol. 97, No. 19, pages 10526-10531, September 12, 2000).

The teachings of Ehrenreich are described above. Ehrenreich does not teach administering EPO dosages at about 2500 IU/kg.

Alafaci et al. teach the administration of EPO 1000 IU in a subarachnoid hemorrhage-induced acute cerebral ischemia animal model. EPO was injected intraperitoneally 5 minutes and continued every 8 hours for 24 hours (page 220, 2nd-4th paragraphs). Alafaci et al. teach fewer damaged neurons in the EPO treated group (Figures 2 and 3, page 221). Brines et al. teach the administration of EPO (5000 IU) in focal ischemia stroke animal model (MCA rat model). Recombinant human EPO was

administered 24 hours before, simultaneously, or 3, 6, or 9 hours after MCA occlusion. Brines et al. teach reduced infarction volume (page 10529, 1st paragraph and Figure 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treating cerebral ischaemia comprising intravenously administering rhEPO in dosage amounts from 5,000 to 100,000 units within 8 hours, 24 hours and 48 hours after the stroke as taught by Ehrenreich, to include dosages at about 2500 IU with a reasonable expectation of success. The motivation and expected success is provided by Alafaci et al. and Brines et al. Alafaci et al. teach fewer damaged neurons in a subarachnoid hemorrhage-induced acute cerebral ischemia animal model treated with EPO in a dosage amount of 1000 IU. Brines et al. teach that the quantity of rhEPO (5,000 IU) administered in the MCA occlusion studies is much higher than that needed for erythropoiesis and substantially higher than most conventional clinical dosages (page 10531). Furthermore, one of ordinary skill in the art of designing a dosing regimen for treatment would have been motivated to modify Ehrenreich et al. to include adjustments of conventional working conditions such as dosages, time, etc. because these modifications are deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
5/1/07

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER 5/4/07

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